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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,108	09/29/2000	Lynn Joens	M0-4890	2035

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BAYER CORPORATION
PATENT DEPARTMENT
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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/10/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/677,108

Applicant(s)

JOENS, LYNN

Examiner

Robert A Zeman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 8-21, 23-25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) 8-21 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed on 8-5-2002 is acknowledged. Claims 1-2, 6-7, 22 and 26 have been canceled. Claims 27-31 have been added. Claims 8-21 and 23-25 remain withdrawn from consideration. Claims 3-5 and 27-31, to the degree they read on whole culture vaccines and inactivated culture vaccines, are currently under examination.

This application contains claims 8-21 and 23-25 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Objections Withdrawn

The objection to claim 2 for reciting material drawn to non-elected inventions is withdrawn. Cancellation of said claim has rendered the objection moot.

Objections Maintained

The objection to the specification for the improper use of trademarks is maintained for reasons of record. The amendment to the specification is insufficient to overcome said objection. Each instance should not only be capitalized **but also accompanied by the generic terminology.**

Claim Rejections Withdrawn

The rejection of claim 22 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting a porcine from disease caused by *L. intracellularis*, does not reasonably provide enablement for methods of protecting other mammals, including man, from disease caused by *L. intracellularis* is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claims 1 and 26 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by use of the phrase “antigens selected from the group consisting of 21 kDa, 31 kDa, 41 kDa, 43 kDa, 44 kDa, 60 kDa, 71 kDa, 115 kDa and > 115 kDa” is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 1 and 26 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “producing antibodies” is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 6 and 7 under 35 U.S.C. 112, second paragraph for containing trademark/trade names is withdrawn. Cancellation of said claims has rendered the rejection moot.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Joens et al (U.S. Patent 5,610,059 – IDS-4) for the reasons set forth in the previous Office action in the rejection of claims 1, 2 and 26.

Applicant argues:

1. The cited reference did not disclose experimental results showing protection or even antibody production.
2. All references to vaccines or methods of using said vaccines were prospective.
3. Only the isolated agent and its infectivity find support in said reference.

Applicant's arguments have been fully considered and deemed non-persuasive.

As outlined in the previous Office action, the rejected claims are drawn to a proliferative ileitis vaccine comprising **tissue culture grown *L. intracellularis* or an inactivated culture of *L. intracellularis*** i.e. they are drawn to the whole organism. The ability to produce antibodies would be an inherent property of the microorganisms (vaccine composition) since cell preparations would comprise all the antigens of the *L. intracellularis*. Additionally, recitation of the term "vaccine" in the instant claims is intended use and does not distinguish over the composition of Joens et al. Therefore, contrary to Applicant's assertion, since Joens et al. disclose all the limitations of the rejected claims it is anticipatory of said claims.

Claims 3-4 and 27-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Joens et al (U.S. Patent 5,610,059 – IDS-4) for the reasons set forth in the previous Office action in the rejection of claims 1-4, 22 and 26.

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The rejected claims are drawn to a proliferative ileitis vaccine comprising tissue culture grown *L. intracellularis* or an inactivated culture of *L. intracellularis* and a method of using said vaccine to protect a mammal from the disease caused by *L. intracellularis*.

Applicant argues:

1. The cited reference did not disclose experimental results showing protection or even antibody production.
2. All references to vaccines or methods of using said vaccines were prospective.
3. Only the isolated agent and its infectivity find support in said reference.

Applicant's arguments have been fully considered and deemed non-persuasive for the reasons set forth above. Additionally it should be noted that Joens et al. disclose methods of propagating *L. intracellularis* in Henle 407 cells. The isolated *L. intracellularis* further disclosed to be inoculated into porcines in order to check its pathogenicity (see examples 1 and 2). Additionally, Joens et al. disclose that said the *L. intracellularis* culture could be used to develop a "bacterin" using techniques known in the art such as heat treatment or chemical inactivation (see column 4, lines 6-16). Finally, Joens et al. disclose that said bacterin could be administered to porcines to "permit the pigs to mount an effective immune response against the agent (PPE)". Therefore, contrary to Applicant's assertion to the contrary, all limitations of the instant invention are disclosed by Joens et al. or would have been obvious to one of skill in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joens et al (U.S. Patent 5,610,059 – IDS-4) for the reasons set forth in the previous Office action in the rejection of claims 1-7, 22 and 26.

The rejected claims are drawn to a proliferative ileitis vaccine comprising tissue culture grown *L. intracellularis* or an inactivated culture of *L. intracellularis* and optionally comprise an adjuvant. Said cultures being inactivated with heat, freeze/thaw or chemical treatment.

Additionally, the rejected claims are drawn to a method of using said vaccine to protect a mammal from the disease caused by *L. intracellularis*.

Applicant argues:

1. The fact that Joens et al. disclose, “the *L. intracellularis* culture could be used to develop a bacterin using techniques known in the art...” does not provide an enabling disclosure.
2. There is nothing in the disclosure of Joens et al. to support a reasonable expectation of success in preparing an effective vaccine.

Applicant’s arguments have been fully considered and deemed non-persuasive for the reasons set forth above. Additionally, as outlined in the previous Office action, Joens et al. disclose methods of propagating *L. intracellularis* in Henle 407 cells. The isolated *L. intracellularis* is further disclosed to be inoculated into pigs in order to check its pathogenicity (see examples 1 and 2). This injection, regardless of the motivation for performing it, would initiate an immune response that would include antibody production. Additionally, Joens et al. disclose that said the *L. intracellularis* culture could be used to develop a “bacterin” using techniques known in the art

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such as heat treatment or chemical inactivation (see column 4, lines 6-16). Contrary to Applicant's assertion, utilizing techniques known in the art to perform a disclosed procedure fulfills the requirements of 35 U.S.C. 112, first paragraph. Finally, the disclosure Joens et al. disclose that said bacterin could be administered to pigs to "permit the pigs to mount an effective immune response against the agent (PPE) would provide one of skill in the art not only of a reasonable expectation of success but a motivation to use the disclosed composition as a vaccine.

New Objections

Claim 27 is objected to as reciting material drawn to non-elected inventions. The elected invention is drawn to whole culture vaccines and inactivated culture vaccines.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991.

The examiner can normally be reached on M-Th 7:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
October 7, 2002


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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